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Sent: Thursday, August 05, 2010 9:54 AM
To: wvsdml_digitek_chambers@wvsd.uscourts.gov
Cc: Dean, Richard; Moriarty, Matthew; Thompson, Fred; carln@facslaw.com; mmcdonough@shb.com; Rebecca Betts; hkaplan@shb.com
Subject: Digitek Products Liability Litigation, MDL No. 1968
Attachments: Ltr to Judge Goodwin.pdf; Settlement Terms.doc\$

I apologize for any inconvenience. Attached is the August 4, 2010 letter to Judge Goodwin along with the confidential term sheet. Please contact me if you have any questions. Thank you.

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August 4, 2010

VIA E-MAIL (wvsdml_digitek_chambers@wvsd.uscourts.gov)

Honorable Joseph R. Goodwin, Chief Judge
United States District Court for the
Southern District of West Virginia
7009 Robert C. Byrd United States Courthouse
300 Virginia Street East
Charleston, WV 25301

Re: *In re Digitek[®] Products Liability Litigation*, MDL No. 1968

Dear Judge Goodwin:

The meeting that the parties have requested for Thursday morning is designed to update you regarding the status of the settlement negotiations and the litigation overall, and to seek your guidance on the next steps. This letter is the Defendants' perspective on how we arrived at the current situation, a summary of proposed settlement terms, and some of the issues we face going forward.

HOW WE GOT HERE

This is a manufacturing defect products liability case involving one drug - Digitek[®]. After discovery was well under way, and the facts, theories, and cost of this litigation were apparent, the parties started settlement discussions. We ultimately came to you so that you knew about these discussions and to ensure that the PSC leadership had your approval to proceed. Up to that point there was little, if any, evidence that defective Digitek[®] had been distributed to consumers. In fact, in a rare move, the FDA has gone on record stating that: "In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely." FDA Website in Report entitled "Facts & Myths About Generic Drugs" (Defendant's Exhibit 38).

Plaintiffs' deadline for the identification of general liability experts was June 15, 2010. By that deadline the Plaintiffs identified 6 experts, and their reports are available if you wish to read them. In essence, each of the 6 experts opine that Actavis Totowa LLC violated the FDA's

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cGMP regulations, leading to their conclusions that Actavis Totowa's products were adulterated within the meaning of the Food Drug and Cosmetic Act. (The PSC's experts do not talk about negligence, out-of-specification Digitek®, or defective Digitek® in their reports.)

The FDA's position, as stated on its own website, is that "adulterated" does not mean that the products were out-of-specification or defective. (See Food and Drug Administration, "Facts About Current Good Manufacturing Practices (cGMPs)," <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm> (last visited August 3, 2010)). A number of Courts had said the same thing in their written opinions. Two examples are *Krueger v. Johnson and Johnson Professional, Inc.*, No. 4:00-cv-10032, 2002 WL 34371190 (S.D. Iowa Sept. 10, 2002) and *United States v. Lit. Drug Co.*, 333 F. Supp. 990, 998 (D. N.J. 1971)).

Between June 28 and July 1, 2010, the Defendants deposed 4 of the Plaintiffs general liability experts. They collectively conceded:

- The Digitek® recall was for the possibility that double thick tablets may have been released, and that only one recalled batch – 70924 – was known to have any;
- Double thick tablets are a significantly different pharmaceutical manufacturing problem from tablets with normal size but varying amounts of the active pharmaceutical ingredient (here, digoxin);
- The FDA never found or warned Actavis that Digitek® had problems with tablets of normal size but varying, out-of-specification, active pharmaceutical ingredient;
- There is no evidence that Actavis manufactured Digitek® of normal size with varying degrees of active pharmaceutical ingredient;
- The recall of a product does not automatically mean that the product was defective;
- That product is considered adulterated does not automatically mean the product was defective;
- They have no opinion to a reasonable probability that defective Digitek® made it to the hands of consumers.

Defendants will be glad to provide these transcripts, or excerpts, if the Court wishes.

After these initial 4 depositions, the lawyers for the Plaintiffs and the Actavis entities increased the pace of the settlement discussions, ultimately culminating in a verbal agreement in

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principle. The *Kelch* case, first on the MDL trial list, was settled separately. The parties approached the Court on July 12, 2010, requesting a 30-day stay of discovery. Since then, the lawyers have met in person twice and exchanged many phone calls and e-mails. The verbal agreement has now been reduced to a term sheet, and a draft settlement agreement has been exchanged.

BASIC TERMS

The confidential term sheet is attached. Basically, Actavis will deposit \$10 million into a fund to compensate consumers who satisfy certain criteria. All cases and tolled claims in the MDL are automatically included, with a right to opt-out. To be binding on both sides, the PSC needs to obtain the participation of 85% of the filed MDL lawsuits and a higher percent to be determined of the claimants subject to tolling agreements. The program of assessing the actual claims to the fund will be administered by a Special Master, with consultation available from a nurse and physicians. Actavis will pay for the administrative expenses of the fund up to \$2 million. Lawyers in the state cases will be encouraged to join this program. The fee contracts of the Plaintiffs' lawyers apply to any awards made by the Special Master.

The PSC can apply to the Court for recovery of reasonable fees and expenses for the prosecution of this MDL. Defendants reserve the right to contest the award in its entirety. The parties will live with your decision in that regard with no right of appeal.

If this agreement is implemented, the Defendants intend to move the Court for a *Lone Pine* Order, applicable to the remaining opt-out cases, similar to the *Lone Pine* Order Judge Fallon entered for non-settling Plaintiffs in the Vioxx litigation. The 5th Circuit Court of Appeals recently affirmed that Order. (Defendants will have copies of Judge Fallon's Order available tomorrow.) Given the lack of any evidence of product defect after all of this time, the Defendants feel that, at this juncture of the litigation, such an order would be the most efficient way to bring the remainder of the MDL docket to conclusion.

WHERE WE ARE HEADED

Defendants seek the Court's guidance on three key issues:

- First, what is the best way to establish the opt-out period?
- Second, what should be done about existing deadlines for MDL discovery and *Daubert* briefing?
- Third, what steps can be taken by the MDL court to continue coordination with the state court judges? It is our preliminary understanding that the MDL *Vega* case, and the cases in Philadelphia, may not participate in this settlement. We do not know what position the New Jersey and Texas lawyers will take and are uncertain as to

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how much they know about the proposed settlement. As a result, there may still be a need for a *Daubert* hearing on October 13th and 14th as scheduled. Given that possibility, we attach thoughts about a proposed format for that hearing.

We look forward to seeing you and discussing these issues. Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Matthew P. Moriarty". The signature is fluid and cursive, with a large initial "M" and a long, sweeping underline.

Matthew P. Moriarty

MPM:rcf

cc (via e-mail):

Fred Thompson
Carl Frankovitch
Madeleine McDonough
Rebecca Betts
Dick Dean
Harvey Kaplan

DAUBERT HEARING SUGGESTIONS

EXPLANATION OF KEY ISSUES

Oftentimes in product liability litigation, the general causation question is whether a given drug or chemical is capable of causing a specific condition, *i.e.*, does Benedectin cause a specific type of birth defect – the question at issue in *Daubert*. But this is a manufacturing defect case where defendants deny that any defective Digitek® left the factory and reached the market. The general causation question in such a case is whether consumers were exposed to any such defective product and the level at which such exposure is hazardous to human beings generally. The testimony of plaintiff's general liability experts demonstrates either (1) a concession that they have no evidence of defective product reaching the market or (2) lack of a reasonable methodology for concluding otherwise. As a result, one key issue the Court should consider is the evidence and basis for opinions as to whether defective Digitek® reached the market. If there is no such evidence, there is no basis for the litigation going forward.

The second issue is one of medical causation, more specifically whether medical physicians have a reasonable basis to express opinions about defect from a review of medical records. Defendants will present Dr. Walter Kernan from Yale University to explain the background of the drug, how it is used, and how perfectly made digoxin can result in high digoxin levels.

Defendant would also propose that one hour be set aside to examine one federal case and one hour to examine a Philadelphia case. Each side would be given 30 minutes to present their views and apply general principles discussed on the first day to actual cases.

PROPOSED SCHEDULE

October 13th

9:00-9:15	Defendant's overview of issues and witnesses they will present.
9:15-9:30	Plaintiff's overview of issues and witnesses they will present.
9:30-10:00	Presentation by Defendants of proof of lack of evidence to establish defective tablets. Use of summary charts.
10:00-10:30	30 minute video with highlights of Plaintiffs' experts conceding no proof of defective tablets.
10:30-10:45	Break
10:45-11:45	Direct and cross exam Lew Amsel – Defendants' manufacturing expert.
12:00-1:30	Lunch
1:30-1:45	Overview by Defendants of multiple causes of digoxin toxicity and why medical physicians can have no reasonable basis to express opinion on product defect.

1:45-2:45 Direct exam and cross examination of Dr. W. Kernan explaining cause of digoxin toxicity with normal tablets and why no defect can be assumed from high serum digoxin levels.

3:00-5:00 Plaintiffs' presentation of evidence on their theories of proof of defect including Defendants' cross-examination of any witness.

(Plaintiffs to identify witnesses to Defendants by Sept. 1.)

October 14th

9:00-10:30 Presentation of one Federal case. (Probably *Vega*.)

9:00-9:45 Defendants' presentation.

9:45-10:30 Plaintiffs' presentation.

10:30-10:45 Break

10:45-12:15 Presentation of one Philadelphia case (to be determined.)

10:30-11:15 Defendants' presentation.

11:15-12:00 Plaintiffs' presentation.

12:15-1:30 Lunch

1:30-2:30 30 minute summaries by both sides.

2:30 Judges Conference

SETTLEMENT TERMS

Defendants, Actavis Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, Inc., have agreed to establish a fund of Ten Million Dollars (\$10,000,000.00) for the resolution of cases meeting the criteria set forth below. Many of the words and phrases will be defined in the settlement agreement. The parties continue to negotiate the terms and details of every aspect of the agreement.

1. Entry Criteria. To be available to participate in the fund the Plaintiff must meet all of the below criteria.

1. Plaintiff must have a timely filed or tolled case as of June 1, 2010 (does not make sense, as phrased); and
 2. Participating plaintiff will be required to have proof by medical records and/or prescription of use of recalled Digitek manufactured during the period of March, 2006 to April, 2008; and
 3. A medically definable incident (ER visit, doctor's visit, healthcare intervention, etc...); and
 4. Plaintiff must have one of the following:
 - I. A clinical diagnosis of digoxin toxicity in a contemporaneous medical record at the time of the medically definable incident as described in 3 above; and/or
 - II. An elevated serum digoxin concentration of 2.6 or higher in reasonable proximity to the medically definable incident described in 3 above; and/or
 - III. A qualified physician's affidavit supported by contemporaneous medical records attesting to a probable digoxin related illness or injury at the time of the medically definable incident.
2. In those instances in which an affidavit is submitted without a contemporaneous clinical diagnosis of digoxin toxicity and/or elevated serum digoxin concentration 2.6 or higher, the claim will be submitted to a medical consultant for review and be evaluated on an individual basis to confirm the validity of the medical opinion submitted.
3. The election to participate in the settlement program shall be non-revocable and not subject to any appeal.

CONSIDERATIONS

1. Product use and product identification can be established by pharmacy records, doctor records, hospital records or independent tablet verification by the defense.
2. Serum digoxin concentrations must be drawn in accordance with generally accepted standards and must be drawn no sooner than 6 hours after the last dose. Post-mortem blood digoxin levels will be independently considered by the medical panel.
3. Proof of defect. Any claimant who can submit proof of defective tablets by certified measurements or reliable laboratory testing shall be entitled to enhanced payment.
4. Claims participating in the fund established by the defendants will be assigned points to determine the extent of payment. Claimants who have met the initial criteria shall be assigned a basic point value of 100 points which shall be reduced or augmented by the followings:

Basic Entry Case = 100 points

ADDITIONS (caused by Digitek related incident)	
1. Death	+ 200
2. Extensive Medical Specials	+ 10 - 50
3. Patient Age Under the age of 50	+ 10
4. Hospitalization more than 3 days	+ 20
5. Loss of Consortium/ Minor Children/ Dependents	+ 10 - 50
6. Lost wages	+ 10 - 50
7. Proof of Defect	+ 100
8. Pacemaker (caused by Digitek incident)	+ 75
9. Asystole (flat line/ no cardiac electrical activity)	+ 50
10. Mild Arrhythmia or heart block Slow heart rate from AV block or sinus Slow heart rate from sinus bradycardia Premature beats Premature ventricular contractions Sino atrial node conduction disturbances Atrio-ventricular node conduction disturbances EKG manifestations Junctional or ventricular tachycardia	+ 50
11. Serious Arrhythmia or advanced heart block Atrial ectopic arrhythmias ventricular ectopic arrhythmias Brady arrhythmias	+ 100

Tachyarrhythmias junctional or ventricular fibrillation	
12. Special Circumstances	+ 10 - 50

Additions not to exceed 260 points
excluding cases with proof of defect or death

DEDUCTIONS (factors that may cause Digoxin toxicity)	
1. Patient age (Neutral 50 - 60) 60 – 69 70 – 75 76 +	-5 -10 -15
2. Underlying Heart Problems or Disease Excludes conditions treated with Digitek such as CHF or a-fib Includes myocardial ischemia, ischemic heart disease, acute coronary syndrome, structural problems etc	-15
3. Co-morbidities and/or contributing medical history Examples include diabetes, hypertension, pulmonary or vascular disease, thyroid disease	-10
4. Impaired Renal Status (pre-existing)	-15
5. Other acute conditions which may affect Digoxin levels Includes dehydration, hypomagnesemia, hypercalcemia, hypokalemia	-10
6. Other medications that may contribute to Digoxin toxicity or increase serum digoxin concentration (exemplar list attached) Alprazolam (Xanax) Amiodarone (Cordarone) Clarithromycin (Biaxin) Diphenoxylate (with atropine; Lomotil) Erythromycin Indomethacin (Indocin) Propafenone (Rythmol) Propantheline (Pro-Banthine) Quinidine Rifampin (Rifadin) Tetracycline Verapamil (Calan)	-10

Minimum base score is 30 points regardless of deductions

Claims of participating claimants shall be submitted to an independent claim facility which shall accumulate the information to establish an evaluation of the claims. Claims shall be evaluated and assigned the point additions and deductions as set forth above. The total number of points for qualifying claimants shall determine the percentage of participation for each claimant in relation to the Ten Million Dollar (\$10,000,000.00) Fund.

All administrative costs and expenses attendant to the administration of the claims facility shall be born by the defendants, up to a maximum of \$2,000,000. It is agreed by the parties that the Plaintiffs' Steering Committee shall have the right to submit to the Court time and expenses expended in the pursuit of this action. The Defendants have the right to contest any or all of such requests. The Honorable Judge Joseph Goodwin shall award such fees and costs as he deems appropriate, which amount shall be non-appealable by either party.

The defendants reserve the right to withdraw the proposed settlement in the event that less than 85% of the currently filed cases affirmatively decline to participate in the settlement, and ___% of the tolled claims.

Cases filed in state courts will have the option to participate in this agreement and program.